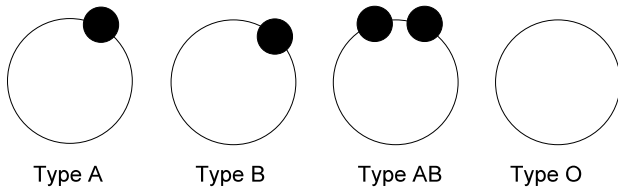


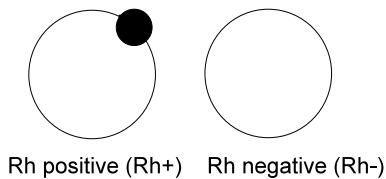
RhoGAM Authorization/Refusal

What does it mean to be Rh negative?

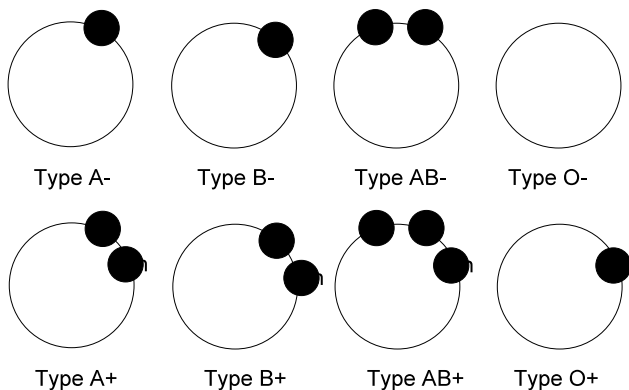
Everyone has different types of proteins on their red blood cells. One set of proteins are type A or B. If you have A proteins on your red blood cells, your blood type is A. If you have B proteins, your blood type is B. If you have both, your blood type is AB. If you have neither type A or B proteins on your red blood cells, your blood type is O.



The Rh protein, officially called the Rhesus protein, is a different protein that may or may not be on your red blood cells. If you have the Rh protein on your blood cells, you are said to be *Rh positive* (Rh+). If you do not have Rh proteins on your blood cells, you are said to be *Rh negative* (Rh-).



To together, the A and B proteins and the Rh proteins determine your blood type.

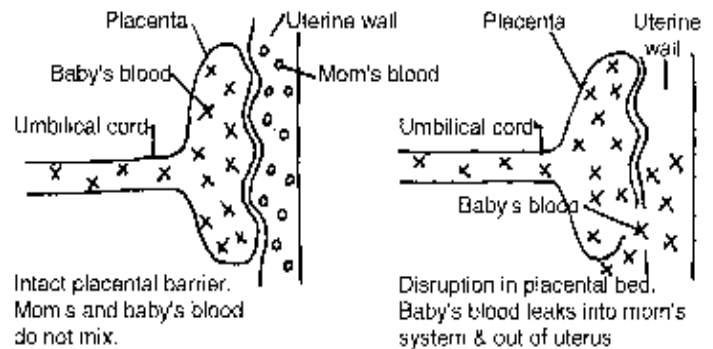


Why is being Rh negative a problem?

When we are developing in the womb, our bodies take stock of all the proteins that are present and come to the conclusion that those proteins are "self," meaning that they belong there and are acceptable. Proteins that are not present during this critical period are by exclusion labeled "non-self" by the body. If one of these proteins later presents itself, the body may create *antibodies* against it. Antibodies are like the body's soldiers that are sent out to hunt and destroy any foreign invaders.

If your blood type is Rh-, the Rh protein is considered by your body to be non-self, a foreign invader, and it will create antibodies to seek and destroy any red blood cells presenting the Rh protein. When an Rh- mother is pregnant with an Rh+ baby, the Rh proteins on the baby's blood cells are foreign to the mother's body. Normally, the blood of the baby and the mother are kept separate by the placenta so that the two blood systems never mix.

However, there are some times when some red blood cells of the baby's can leak into the mother's system. For example, if the placenta is disturbed and tears slightly or peels back away from the mother's uterus a little bit (or a lot), blood from the baby's side of the placenta can find its way into the mother's bloodstream. Usually when that happens you will see bleeding to alert you that something is wrong, but not always. Of course, when the placenta naturally separates after the birth of the baby, it is very possible for some of the baby's blood to get into the mother's system.



When this type of leakage occurs, the mother's body can begin to create antibodies to kill off the invading blood cells from the baby. Unfortunately, these antibodies can cross the placental barrier and once inside the baby, they begin to attack the baby's blood cells there as well. Depending on how vigorous a defense the mother's body mounts, the damage to the baby may be mild to severe. In some cases it may even kill the baby.

Of course, if the baby is already born the mother's antibodies will never reach the baby because the baby is no longer connected to her through the placenta and umbilical cord. But a future baby could be affected because, if it has Rh+ blood and any gets into the mother's system during the pregnancy, the antibody soldiers will be called out to start the extermination war.

We call the mother's antibody response to Rh protein exposure *Rh sensitization*, or *Rh isoimmunization*.

How can I prevent Rh sensitization?

If you are Rh-, it is important to know the blood type of the biological father of your baby. Two Rh- parents cannot produce an Rh+ child, so if both mother and father are Rh-, you will not need to worry about Rh sensitization. However, if the father of the baby is Rh+, there is at least a 50% chance that each baby you carry by that father will be Rh+.

If there is any chance your baby could be Rh+, it is critical you alert your care provider to any vaginal bleeding you experience during your pregnancy, because it could indicate an opportunity for sensitization. It is also important that you tell your care provider about any certain or possible miscarriages prior to this pregnancy, because sensitization could have occurred then also.

Your care provider should do a blood test early in your pregnancy to determine if you have become Rh sensitized. If that test comes back ok, you only have to worry about bleeding during this pregnancy, not past pregnancies.

If you have any uterine bleeding during this pregnancy, you can receive an injection of Rho D Immunoglobulin (also called RhoGAM®) to help prevent sensitization. RhoGAM contains, ironically enough, antibodies to the Rh protein. Because these antibodies were not produced by your body, they do not multiply and they do not stay in your system forever. Their job is to hunt down any Rh+ blood cells that have leaked into your body, destroy them, and then eventually die out themselves. The idea is that these external antibodies destroy any Rh+ blood cells before your own body has a chance to recognize them and create its own antibodies. They sort of erase the invasion and your body never knows it occurred. Even though the RhoGAM antibodies can cross the placenta, they are limited in number and they cannot cause significant damage to the baby.

Because Rh sensitization most often occurs when the placenta separates at the time of birth, it is important to receive RhoGAM within 3 days after an Rh+ baby is born if you wish to prevent sensitization. If the baby's blood type turns out to be Rh-, you do not need to receive RhoGAM because there are no offending Rh proteins on the baby's blood which might cause sensitization. RhoGAM is highly effective (although not 100%) at preventing sensitization when given within 72 hours postpartum. If no RhoGAM is given, the odds of becoming sensitized are 16%¹. If RhoGAM is given within 72 hours, the odds of becoming sensitized are 1.8%²

RhoGAM can also prevent sensitization after a miscarriage. If no RhoGAM is given within 72 hours following miscarriage, the odds of becoming sensitized are 2% if the miscarriage is completed spontaneously, 5% if there is a D&C.³

What's this I hear about RhoGAM at 28 weeks?

While most sensitizations occur as the result of placental separation at birth, it is possible to have "silent bleeds" earlier in pregnancy which are not detectable by the mother, but through which sensitization can nonetheless occur. These "silent sensitizations" occur in about 2% of pregnancies of Rh- women.

The standard solution to this problem is to give Rh- mothers a small injection of RhoGAM at 28 weeks. By giving RhoGAM at 28 weeks in addition to giving it postpartum, the incidence of sensitization drops from 1.8% (approximately 2 women out of a hundred) to 0.1% (1 in a thousand).⁴

What else affects Rh sensitization?

Interestingly, mothers whose babies have an incompatible major blood type experience some protection from Rh isoimmunization. That is, if the baby's blood has A or B proteins on its cells that are foreign to the mother, and the blood leaks into her system, usually her A or B antibodies destroy the blood so quickly that her Rh antibodies do not have time to recognize the invasion. (Rh antibodies are slower than A or B antibodies.) When the baby is A or B incompatible, there is only a 2% chance of sensitization by 6 months postpartum when no RhoGAM is given⁵ (versus 16% if the baby is A or B compatible). To make it easier to figure out, here is a table showing when you may have some protection because of ABO incompatibility:

If your blood type is...	You have some protection if the baby's blood type is...	But this is only possible if the baby's father is of type...
O	A B	A or AB B or AB
A	B AB	B or AB B or AB
B	A AB	A or AB B or AB

Other factors that affect the likelihood of sensitization are:

- The relative number of Rh proteins on the baby's blood cells
- The amount of baby's blood that leaks into the mother's system
- The relative intensity of the mother's antibody response to invading baby blood cells

These factors are, for the most part, unknowable and uncontrollable.

When else is RhoGAM recommended?

If you want to prevent sensitization, you should get RhoGAM whenever there is a relatively high likelihood of leakage of the baby's blood into yours. Miscarriages, bleeding during pregnancy, and birth are obvious occasions. However, you should also get RhoGAM following amniocentesis (when a needle is inserted through the abdomen into the uterus to withdraw amniotic fluid) and following external version (when a breech baby is turned by manipulating the belly from the outside).

What are possible negative effects of RhoGAM?

RhoGAM contains actual Rh antibodies produced by people who have become sensitized. It is, therefore, a blood product. Current procedures and manufacturing processes are in place to prevent blood-borne pathogens, such as HIV/AIDS and hepatitis from being included in any active form in the RhoGAM you receive. There is, however, a theoretical possibility that these procedures and processes could be ineffective for the batch of RhoGAM you receive, or that there might be a new pathogen that has not yet been identified or disabled in the manufacturing process. This risk is extremely small.

Jehovah's Witnesses and others who belong to religions prohibiting the use of blood products should consult their conscience and possibly ecclesiastical leaders about the use of RhoGAM.

RhoGAM is considered a drug, and is regulated by the FDA. The FDA categorizes all drugs in terms of their relative safety for use in pregnancy. Here is how they are rated:

A--Controlled studies of these drugs in pregnant women have shown no risk to the fetus. Therefore, the possibility of harm to the fetus appears remote. [There are very few drugs that bear this classification. It seems no one is willing to test anything to this extent on pregnant women. Example: folic acid]

B--There has been no evidence of risk in animals, but insufficient information is available about use in humans. This category also includes those drugs that have shown an adverse effect in animals that could not be confirmed in humans. [There are a relatively small number of drugs in this class. Examples are Tylenol, Ampicillin, Insulin]

C--For drugs in this category, risk cannot be ruled out. Human studies are lacking, or animal studies have either demonstrated fetal risk or are lacking as well. However, potential benefits of medications in this category may justify the risk. [Many drugs that are used routinely in pregnancy are in this class. Examples are: Albuterol, Prozac, Acyclovir]

D--Drugs in this category have demonstrated evidence of human fetal risk. Nevertheless, the benefits from use of these drugs during pregnancy may be acceptable despite the risk--for example, if the drug is needed in a life-saving situation or for a serious disease for which safer drugs are not available. [Examples: Methotrexate (anti-cancer drug), Lithium (manic-depressive drug), Aloe (used orally in laxatives)]

X--Drugs in this category should be avoided throughout pregnancy. Studies in animals or humans have shown fetal risk that clearly outweighs any benefit to the patient. [Examples: Marijuana, doxycycline (an antibiotic), anabolic steroids]

RhoGAM is in category C.

It is also possible for allergic reactions to RhoGAM to occur. These reactions may be mild to severe, and can include hives, generalized itching, tightness of the chest, wheezing, low blood pressure and anaphylactic shock. These systemic reactions are extremely rare, and no deaths have ever been reported. In about

1 in 120,000 recipients of RhoGAM, there is a local reaction to the injection, including swelling, hardness, redness, and mild pain at the site of the injection.⁶

Until the last few years, RhoGAM was preserved with thimerisol, a mercury-based preservative that many considered to be harmful to both mother and baby. This preservative is no longer used in RhoGAM, and so is no longer a worry.

How much does RhoGAM cost?

There are two costs involved in RhoGAM. First, is the lab work that is required to determine whether RhoGAM should be given. Then there is the cost of the injection itself. RhoGAM is made from the blood of people who have become sensitized, so it is difficult to produce and sometimes in short supply. That makes it expensive. Check our current payment agreement for prices. Most insurance policies that cover maternity will cover RhoGAM and it's associated lab work, however the percentage they pay verses the percentage you pay may vary widely. You should consult your insurance company if you have questions about their coverage of RhoGAM. Be sure to ask specifically about both the laboratory portion and the medication portion of the fees, because the coverage might be different.

What if I don't get RhoGAM within 72 hours of birth?

We don't know how long after birth a RhoGAM injection can be given and still be effective. The original studies were all based on giving RhoGAM within 72 hours. However, in one study RhoGAM prevented sensitization in 50% of subjects when it was given 13 days after exposure to Rh positive cells.⁷ It is reasonable to think that giving RhoGAM would still be effective for at least some days after the 72 hour period, and if it were not effective, it would at least not be harmful. It would be especially important, in this case, to get the lab work done to determine whether sensitization has already occurred.

Given all you know about RhoGAM and Rh sensitization, please select one of the following options:

References:

1. *Williams Obstetrics*, 20th Edition, 1997, Appleton & Lange, Stamford CT, p. 982.
2. *Ibid.*, pg. 987.
3. *Ibid.*, pg. 986.
4. *Ibid.*, pg. 987.
5. *Ibid.*, pg. 982.
6. Package insert for RhoGAM, Ortho-Clinical Diagnostics, Inc., Johnson & Johnson, Raritan, New Jersey 08869, September 2001.
7. *Ibid.*

RhoGAM is a registered trademark of Ortho-clinical Diagnostics, Inc., a Johnson & Johnson company.

☐ No RhoGAM.

Having read this document and understanding the risks, I choose not to receive RhoGAM at any point during this pregnancy or postpartum. I have had an opportunity to ask questions of my midwife and other providers and I release and hold them, as well as BetterBirth, LLC, harmless for the results of this decision.

Signature

Date

Witness

☐ RhoGAM postpartum only.

Having read this document and understanding the risks, I choose to receive RhoGAM after my baby is born (assuming lab results indicate that RhoGAM is appropriate), but not at 28 weeks gestation. I have had an opportunity to ask questions of my midwife and other providers and I release and hold them, as well as BetterBirth, LLC, harmless for the results of this decision.

Signature

Date

Witness

☐ RhoGAM at 28 weeks and postpartum.

Having read this document and understanding the risks, I choose to receive RhoGAM at approximately 28 weeks gestation and postpartum (assuming lab results indicate that RhoGAM is appropriate). I have had an opportunity to ask questions of my midwife and other providers and I release and hold them, as well as BetterBirth, LLC, harmless for the results of this decision.

Signature

Date

Witness

Placenta	Uterine wall	Placenta	Uterine wall
Baby's blood	Mom's blood		
Umbilical cord	Umbilical cord		
	Baby's blood		
Intact placental barrier. Mom's and baby's blood do not mix.	Disruption in placental bed. Baby's blood leaks into mom's system & out of uterus		

1. *Williams Obstetrics*, 20th Edition, 1997, Appleton & Lange, Stamford CT, p. 982.
2. *Williams Obstetrics*, 20th Edition, 1997, Appleton & Lange, Stamford CT, p. 987.
3. *Williams Obstetrics*, 20th Edition, 1997, Appleton & Lange, Stamford CT, p. 986.
4. *Williams Obstetrics*, 20th Edition, 1997, Appleton & Lange, Stamford CT, p. 987.
5. *Williams Obstetrics*, 20th Edition, 1997, Appleton & Lange, Stamford CT, p. 982.
6. Package insert for RhoGAM, Ortho-Clinical Diagnostics, Inc., Johnson & Johnson, Raritan, New Jersey 08869, September 2001.
7. Package insert for RhoGAM, Ortho-Clinical Diagnostics, Inc., Johnson & Johnson, Raritan, New Jersey 08869, September 2001.